Department of State Health Services
Agenda Item for State Health Services Council
May 12, 2006

Agenda Item Title: Amendments to rules relating to the licensure of food manufacturers, food wholesalers, and warehouse operators; and the licensing of device distributors and manufacturers.

Agenda Number: 5c

Recommended Council Action:
____For Discussion Only

_**X**_ For Discussion and Action by the Council

Background: The Policy, Standards, and Quality Assurance Unit, Foods Group, and Drugs and Medical Devices Group regulate the manufacture and distribution of food and devices in the State of Texas. The amendments are necessary to provide cost recovery for increases due to the General Appropriations Act, Senate Bill 1, 79th Legislature, Regular Session (2005). Article II, Rider 85, makes a portion of the appropriation contingent upon the collection of fees above the Comptroller of Public Accounts' Biennial Revenue estimate. In addition, the sections require updating to be consistent with changes resulting from House Bill 2292, 78th Legislative Session, 2003.

Summary These rules concern the licensing of food manufacturers, food wholesalers, and warehouse operations, §229.182, and the licensing of device distributors and manufacturers, §§229.435, 229.439, 229.441, 229.443, and 229.444, throughout the State of Texas. The amendments provide for increases in the fees for food wholesalers and device distributors with combinations products. The amendments also update and clarify the sections to reflect current licensing procedures and license term durations as well as identification of the state agencies responsible for certain licensing, enforcement and advisory committee functions.

Summary of Stakeholder Input to Date (including advisory committees):

In March 2006, Foods Group stakeholders were notified via email of the proposed rule change.

In April 2006, a meeting of the Device Distributors and Manufacturers Advisory Committee was convened and the proposed amendments to 25 TAC, §§229.435, 229.439, 229.441, 229.443, and 229.444, concerning Licensing of Device Distributors and Manufacturers, were presented to and reviewed by the members of the Committee. The Committee approved the proposed rules without modification and recommended that they be presented to the State Health Services Council for consideration at its May 2006 meeting.

The proposed rules are posted on the Drugs and Medical Devices Group and Foods Group websites.

Proposed Motion: Motion to recommend to HHSC approval for publication of rules contained in agenda item #5c.

Agenda Item Approved by: _____	**Date Submitted**
Presented by: __Julie Loera_____ **Title**: _Manager_	April 26, 2006
Program/Division: _PSQA Foods Group_ **Contact Name/Phone:** _512-834-6670_	

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 229. Food and Drug
Subchapter L. Licensure of Food Manufacturers, Food Wholesalers, and Warehouse Operators
Amendment §229.182
Subchapter X. Licensing of Device Distributors and Manufacturers
Amendment §§229.435, 229.439, 229.441, 229.443, and 229.444

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission (commission), on behalf of the Department of State Health Services (department), proposes amendments to §229.182 concerning licensure of food manufacturers, food wholesalers, and warehouse operators, and §§229.435, 229.439, 229.441, 229.443, and 229.444 concerning licensing of device distributors and manufacturers.

BACKGROUND AND PURPOSE

The Texas Legislature passed the General Appropriations Act, Senate Bill 1, 79th Legislature, Regular Session (2005). Article II, Rider 85, makes a portion of the appropriation contingent upon collection of fees above the Comptroller of Public Accounts' Biennial Revenue estimate. To meet these requirements, a cost recovery fee is included in these amendments.

Programs with regulatory authority over food manufacturers, food wholesalers, and warehouse operators; and device distributors and manufacturers, were evaluated to determine the level of increase in fees based on the following criteria: the date of the last fee increase for the specific program area; the licensee's ability to pay in comparison to average salary of professionals; the percentage of revenue above costs for the specific program; the cost of licenses compared to other similar licenses; and the value added analysis of the license. Additional costs of administration and enforcement of the program, due to a recent legislative increase in pay, longevity pay, and travel reimbursement, were also factored in to determine the direct and indirect costs of each program.

Finally, the sections require updating to be consistent with changes resulting from House Bill 2292, 78th Legislative Session, 2003. The amendments update and clarify the sections to reflect current licensing procedures and license term durations as well as identification of the state agencies responsible for certain licensing, enforcement and advisory committee functions.

SECTION-BY-SECTION SUMMARY

Amendments to §229.182 contain increases in licensing fees for food wholesalers with combination products for initial and renewal applications per location, based upon gross annual sales. Specifically, new §229.182(b)(3)(A) increases the license fee for wholesalers of combination products with gross annual sales of $0.00 - $199,999.99 by $120 for a two-year term; new §229.182(b)(3)(B) increases the license fee for wholesalers of combination products with gross annual sales of $200,000.00 - $499,999.99 by $180 for a two-year term; new §229.182(b)(3)(C) increases the license fee for wholesalers of combination products with gross annual sales of $500,000.00 - $999,999.99 by $240 for a two-year term; new §229.182(b)(3)(D) increases the license fee for wholesalers of combination products with gross annual sales of $1 million - $9,999,999.99 by $300 for a two-year term; and new §229.182(b)(3)(E) increases the license fee for wholesalers of combination products with gross annual sales of greater than or equal to $10 million by $450 for a two-year term.

Amendments to §229.435 remove the reference to one-year license fees changing the reference to two years, and correctly identify the responsible licensing agency as the Department of State Health Services.

Amendments to §229.439 contain increases in fees for device distributor licenses and renewal licenses for distributors with combination products. Amendments to §229.439(a)(1)(A)-(C) remove references to two-year fees related to minor changes within the licensure period. Specifically, §229.439(a)(2)(A) increases the license fee for distributors with gross annual sales of $0 - $199,999.99 by $120 for a two-year term; §229.439(a)(2)(B) increases the license fee for distributors with gross annual sales of $200,000 - $499,999.99 by $180 for a two-year term; §229.439(a)(2)(C) increases the license fee for distributors with gross annual sales of $500,000 - $999,999.99 by $240 for a two-year term; §229.439(a)(2)(D) increases the license fee for distributors of combination productions with gross annual sales of $1 million - $9,999,999.99 by $300 for a two-year term; §229.439(a)(2)(E) increases the license fee for distributors of combination products with gross annual sales of greater than or equal to $10 million by $450 for a two-year term. Amendments to §229.439(a)(3) add a statement about late fees and remove references to two-year fees related to minor changes within the licensure period.

Amendments to §229.441 correctly reflect that the device-related policies of the U.S. Food and Drug Administration are also the policies of the Department of State Health Services. In addition, the amendments recognize that the Executive Commissioner of the Health and Human Services Commission is responsible for any modification or rejection of rules relating to device labeling exemptions adopted under the Federal Food, Drug and Cosmetic Act. References to the "Board of Health" were removed and replaced with "Executive Commissioner of the Health and Human Services Commission" due to the abolishment of the board.

Amendments to §§229.443 and 229.444 correctly reflect that the agency responsible for certain enforcement actions with respect to adulterated and misbranded devices is the Department of State Health Services and that the Executive Commissioner of the Health and Human Services Commission is responsible for oversight of the functions and duties of the Device Distributors and Manufacturers Advisory Committee. Changes were made due to agency name changes and the abolishment of the Board of Health.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each fiscal year of the first five years the sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. Section 229.182 will provide an increase in revenue to the state of $29,100 for Fiscal Years 2007 through 2011. The effect of §229.439 on state government will be an increase in revenue to the state of $71,910 for Fiscal Years 2007 through 2011. Sections 229.435, 229.431, 229.433 and 229.444 do not contain any fiscal implications.

These additional revenues will offset the increased costs associated with the legislative increase in pay, longevity pay, and travel reimbursement. Implementation of the proposed sections will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to small businesses or micro-businesses required to comply with the sections as proposed.

There will be an increase of 30% in the §§229.182 and 229.439 licensing fees for businesses or persons operating as food wholesalers with combination products or as device distributors with combination products. The probable economic cost to persons required to comply with the section as proposed will be an increase in license fees from $120 - $450 for the two-year term of the license. Sections 229.435, 229.431, 229.433 and 229.444 will not affect costs to small businesses, micro-businesses, or persons required to comply with these sections as proposed.

There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections.

The public benefit anticipated as a result of enforcing or administering §229.182 is to generate funding to operate the program to ensure the safety of foods manufactured, stored and distributed to the public.

The public benefit anticipated as a result of enforcing or administering §229.439 is to generate funding to operate the program to continue enforcement of the minimum standards for device distributors and manufacturers, ensuring these medical products are safe and effective for use by the public and consumers. The public benefits for §§229.435, 229.431, 229.433 and 229.444 are continued enforcement of the minimum standards for device distributors and manufacturers, ensuring these medical products are safe and effective for use by the public and consumers.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the pubic health and safety of a state or a sector of the state. This proposal is not specially intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal regarding §229.182 may be submitted to Julie Loera, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division for Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6670, ext. 2145, or by email to Julie.Loera@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

Comments on the proposal concerning §§229.435, 229.439, 229.441, 229.443, and 229.444 may be submitted to Tom Brinck, Policy/Standards/Quality Assurance Unit, Environmental and Consumer Safety Section, Division for Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, (512) 834-6755, ext. 2388, or by email to Tom.Brinck@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §§431.204, 431.222, and 431.276 which require the department to charge fees for issuing or renewing a license or permit; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human

Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed amendments affect the Health and Safety Code, Chapters 431 and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendments)
Single Underline = Proposed new language
[Bold Print and Brackets] = Current language proposed for deletion
Regular Print = Current language
(No change.) = No changes are being considered for the designated subdivision

§229.182. Licensing/Registration Fee and Procedures.

(a) (No change.)

(b) Licensing and registration fees.

(1) - (2) (No change.)

(3) Wholesaler with combination products. A person who is required to be licensed as a food wholesaler under this section and who is also required to be licensed as a wholesale distributor of drugs under §229.252(a)(1) of this title or as a device distributor under §229.439(a)(1) of this title shall pay a combined licensure fee for each place of business. The licensure fee shall be based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices).

(A) For each place of business having combined gross annual sales of $0.00 - $199,999.99, the fees are:

(i) $520 **[$400]** for a two-year license;

(ii) $520 **[$400]** for a two-year license that is amended due to a change of ownership; and

(iii) $260 **[$200]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(B) For each place of business having combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $780 **[$600]** for a two-year license;

(ii) $780 **[$600]** for a two-year license that is amended due to a change of ownership; and

(iii) $390 **[$300]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(C) For each place of business having combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,040 **[$800]** for a two-year license;

(ii) $1,040 **[$800]** for a two-year license that is amended due to a change of ownership; and

(iii) $520 **[$400]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(D) For each place of business having combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,300 **[$1,000]** for a two-year license;

(ii) $1,300 **[$1,000]** for a two-year license that is amended due to a change of ownership; and

(iii) $650 **[$500]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $1,950 **[$1,500]** for a two-year license;

(ii) $1,950 **[$1,500]** for a two-year license that is amended due to a change of ownership; and

(iii) $975 **[$750]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(4) - (9) (No change.)

(c) - (i) (No change.)

§229.435. Licensure Requirements.

(a) General. Except as provided by §229.434 of this title (relating to Exemptions), a person may not engage in the distribution or manufacture of devices in Texas unless the person has a valid license from the Commissioner of the Department of State Health Services (commissioner) for each place of business.

(b) - (c) (No change.)

(d) New place of business. Each person acquiring or establishing a place of business for the purpose of device distribution or manufacturing after the effective date of these sections shall apply to the Department of State Health Services **[Texas Department of Health]** (department) for a license of such business prior to beginning operation.

(e) - (g) (No change.)

(h) License term. Unless the license is amended as provided in subsection (j) of this section or revoked or suspended as provided in §229.440 of this title (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license is valid for two years **[one or two years as determined by the department]**.

(i) - (m) (No change.)

§229.439. Licensure Fees.

(a) License fee.

(1) No person may operate or conduct business as a device distributor without first obtaining a license from the department. All applicants for a device distributor license or a renewal license shall pay a licensing fee. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on gross annual device sales.

(A) For a distributor with gross annual device sales of $0 - $499,999.99, the fees are:

(i) - (ii) (No change.)

(iii) $240 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(B) For a distributor with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) – (ii) (No change.)

(iii) $540 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(C) For a distributor with gross annual device sales greater than or equal to $10 million, the fees are:

(i) - (ii) (No change.)

(iii) $840 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(2) A person who is required to be licensed as a device distributor under this section and who is also required to be licensed as a wholesale drug distributor under §229.252(a)(1) of this title (relating to Licensing Fee and Procedures) or as a wholesale food distributor under §229.182(a)(3) of this title (relating to Licensing Fee and Procedures) shall pay a combined licensure fee for each place of business. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices).

(A) For each place of business having combined gross annual sales of $0 - $199,999.99, the fees are:

(i) $520 **[$400]** for a two-year license;

(ii) $520 **[$400]** for a two-year license that is amended due to a change of ownership; and

(iii) $260 **[$200]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(B) For each place of business having combined gross annual sales of $200,000 - $499,999.99, the fees are:

(i) $780 **[$600]** for a two-year license;

(ii) $780 **[$600]** for a two-year license that is amended due to a change of ownership; and

(iii) $390 **[$300]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(C) For each place of business having combined gross annual sales of $500,000 - $999,999.99, the fees are:

(i) $1,040 **[$800]** for a two-year license;

(ii) $1,040 **[$800]** for a two-year license that is amended due to a change of ownership; and

(iii) $520 **[$400]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(D) For each place of business having combined gross annual sales of $1 million - $9,999,999.99, the fees are:

(i) $1,300 **[$1,000]** for a two-year license;

(ii) $1,300 **[$1,000]** for a two-year license that is amended due to a change of ownership; and

(iii) $650 **[$500]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(E) For each place of business having combined gross annual sales greater than or equal to $10 million, the fees are:

(i) $1,950 **[$1,500]** for a two-year license;

(ii) $1,950 **[$1,500]** for a two-year license that is amended due to a change of ownership; and

(iii) $975 **[$750]** for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(3) No person may operate or conduct business as a device manufacturer in this state without first obtaining a license from the department. All applicants for a device manufacturer license or renewal license shall pay a licensing fee. All fees are nonrefundable. Licenses are issued for two-year terms. A license shall only be issued when all past due fees and delinquency fees are paid. License fees are based on gross annual device sales.

(A) For a manufacturer with gross annual device sales of $0 - $499,999.99, the fees are:

(i) – (ii) (No change.)

(iii) $240 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(B) For a manufacturer with gross annual device sales of $500,000 - $9,999,999.99, the fees are:

(i) – (ii) (No change.)

(iii) $1,080 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(C) For a manufacturer with gross annual device sales greater than or equal to $10 million, the fees are:

(i) – (ii) (No change.)

(iii) $1,800 for a **[two-year]** license that is amended during the current licensure period due to minor changes.

(b) - (d) (No change.)

§229.441. Minimum Standards for Licensure.

(a) Minimum requirements. All distributors or manufacturers of devices engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of devices must comply with the minimum standards of this section in addition to the statutory requirements contained in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act). For the purpose of this section, the policies described in the United States Food and Drug Administration's (FDA's) Compliance Policy Guides as they apply to devices shall be the policies of the Department of State Health Services **[Texas Department of Health]** (department).

(b) - (f) (No change.)

(g) Device labeling exemptions. Device labeling or packaging exemptions adopted under the Federal Food, Drug, and Cosmetic Act, as amended, shall apply to devices in Texas except insofar as modified or rejected by rules of the Executive Commissioner of the Health and Human Services Commission **[Texas Board of Health (board)]**.

(h) - (l) (No change.)

§229.443. Enforcement and Penalties.

(a) Inspection.

(1) To enforce these sections or the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 (Act), the Commissioner of the Department of State Health Services (commissioner), an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(A) enter at reasonable times a place of business, including a factory or warehouse, in which a device is manufactured, assembled, packed, or held for introduction into commerce or held after the introduction;

(B) enter a vehicle being used to transport or hold a device in commerce; or

(C) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

(2) – (4) (No change.)

(b) - (d) (No change.)

(e) Adulterated and misbranded device. If the Department of State Health Services **[Texas Department of Health]** (department) identifies an adulterated or misbranded device, the department may impose the applicable provisions of Subchapter C of the Act including, but not limited to: detention, emergency order, recall, condemnation, destruction, injunction, civil penalties, criminal penalties, and/or administrative penalties. Administrative and civil penalties will be assessed using the Severity Levels contained in §229.261 of this title (relating to Assessment of Administrative or Civil Penalties).

§229.444. Device Distributors and Manufacturers Advisory Committee.

(a) The committee. An advisory committee shall be appointed under and governed by this section.

(1) The name of the committee shall be the Device Distributors and Manufacturers Advisory Committee (committee).

(2) The committee is required to be established by the Executive Commissioner of the Health and Human Services Commission **[Texas Board of Health (board)]** by Health and Safety Code, §431.275 and is subject to the Health and Safety Code, §11.016.

(b) (No change.)

(c) Purpose. The purpose of the committee is to provide advice to the Executive Commissioner of the Health and Human Services Commission **[board]** in the area of licensure of device distributors and manufacturers.

(d) Tasks.

(1) The committee shall advise the Executive Commissioner of the Health and Human Services Commission **[board]** concerning rules relating to licensing of device distributors and manufacturers.

(2) The committee shall advise the Executive Commissioner of the Health and Human Services Commission **[board]** in the development of standards and procedures relating to the licensing of device distributors and manufacturers; make recommendations to the Executive Commissioner of the Health and Human Services Commission **[board]** relating to the content of the rules adopted to implement the licensing of device distributors and manufacturers; and perform any other functions requested by the Executive Commissioner of the Health and Human Services Commission **[board]** to implement and administer the rules regarding the licensing of device distributors and manufacturers.

(3) The committee shall carry out any other tasks given to the committee by the Executive Commissioner of the Health and Human Services Commission **[board]**.

(e) Review and duration. By September 1, 2007, the Executive Commissioner of the Health and Human Services Commission **[board]** will initiate and complete a review of the committee to determine whether the committee should be continued, consolidated with another committee, or abolished. If the committee is not continued or consolidated, the committee shall be abolished on that date.

(f) Composition. The committee shall be composed of five members appointed by the Executive Commissioner of the Health and Human Services Commission **[board]**. The composition of the committee shall include:

(1) - (3) (No change.)

(g) (No change.)

(h) Officers. The committee shall elect a presiding officer and an assistant presiding officer at its first meeting after August 31st of each year.

(1) (No change.)

(2) The presiding officer shall preside at all committee meetings at which he or she is in attendance, call meetings in accordance with this section, appoint subcommittees of the committee as necessary, and cause proper reports to be made to the Executive Commissioner of the Health and Human Services Commission **[board]**. The presiding officer may serve as an ex-officio member of any subcommittee of the committee.

(3) - (6) (No change.)

(i) - (k) (No change.)

(l) Procedures. Roberts Rules of Order, Newly Revised, shall be the basis of parliamentary decisions except where otherwise provided by law or rule.

(1) - (4) (No change.)

(5) Minutes of each committee meeting shall be taken by department staff.

(A) A draft of the minutes approved by the presiding officer shall be provided to the Executive Commissioner of the Health and Human Services Commission **[board]** and each member of the committee within 30 days of each meeting.

(B) (No change.)

(m) (No change.)

(n) Statement by members.

(1) The Executive Commissioner of the Health and Human Services Commission **[board]**, the department, and the committee shall not be bound in any way by any statement or action on the part of any committee member except when a statement or action is in pursuit of specific instructions from the Executive Commissioner of the Health and Human Services Commission **[board]**, department, or committee.

(2) The committee and its members may not participate in legislative activity in the name of the Health and Human Services Commission **[board]**, the department or the committee except with approval through the department's legislative process. Committee members are not prohibited from representing themselves or other entities in the legislative process.

(3) - (6) (No change.)

(o) Reports to the Executive Commissioner of the Health and Human Services Commission **[board]**. The committee shall file an annual written report with the Executive Commissioner of the Health and Human Services Commission **[board]**.

(1) The report shall list the meeting dates of the committee and any subcommittees, the attendance records of its members, a brief description of actions taken by the committee, a description of how the committee has accomplished the tasks given to the committee by the Executive Commissioner of the Health and Human Services Commission **[board]**, the status of any rules which were recommended by the committee to the Executive Commissioner of the Health and Human Services Commission **[board]**, and anticipated activities of the committee for the next year.

(2) (No change.)

(3) The report shall cover the meetings and activities in the immediate preceding 12 months and shall be filed with the Executive Commissioner of the Health and Human Services Commission **[board]** each September. It shall be signed by the presiding officer and appropriate department staff.

(p) (No Change.)